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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,472	12/29/2000	Dinesh Mody	GUID-117	7176
36154	7590	03/07/2007	EXAMINER	
LAW OFFICE OF ALAN W. CANNON			SHAY, DAVID M	
942 MESA OAK COURT			ART UNIT	PAPER NUMBER
SUNNYVALE, CA 94086			3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/751,472	MODY ET AL.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on January 31, 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,5-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The examiner has taken official notice of various facts in the previous office action. In the instant response, applicant has not challenged these facts, and thus these officially noticed facts are taken to be admitted prior art (see MPEP 2144.03(C)). The examiner notes the submission of the terminal disclaimers in the response to the obviousness type double patenting rejections of the previous office action. However, as the disclaimers have not yet been processed, the rejections must remain in place until such time as they are processed. The examiner has submitted a request that the disclaimers be processed

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed February 7, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position".

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on “wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22, 49-54, 59-69, 96, 97, 100-105, and 282 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 20-22, 49-54, 59-69, 96, 97, and 100-105, “the step of providing....” lacks positive antecedent basis. Further it is unclear what difference on scope exists between claims 60 and 96. In claim 282 “the flexible tubular member” lacks positive antecedent basis.

Claim 106 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Costello et al.

Claims 106 and 107, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bednarek et al.

See Figures 1-8 and column 5, line 15 to column 13, line 5, especially column 9, line 54 to column 12, line 15.

Claim 225, 240, 243, 246, 248, 249, 253, 293-295, and 297 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sinofsky et al.

See Figures 1-7 and column 8, line 34 to column 4, line 25.

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Claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71, 72, 86, 87, 89-91, 96, 97, 100-105, 296, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al. Bednarek et al teach a method such as claimed (see Figures 1-8 and column 12, lines 15-29) except the maintaining of rotational alignment. Sinofsky et al teach a cardiac ablation device employing a slidably positionable ablation element with a rotationally asymmetric cross section positioned in sheath in a lumen with a complimentary shape wherein the energy can be directionalized. It would have been obvious to the artisan of ordinary skill to employ the rotationally asymmetric cross section lumen and ablative element of Sinofsky et al in the method of Bednarik et al, since this would enable less energy to be used in the procedure, since more of it would be directed towards the tissue while assuring that the operative direction could be reliably pointed towards the tissue of interest, or to include the various types of ablation energy and the various procedural steps of Bednarik et al in the method of Sinofsky et al, since the various energies are equivalents, as taught by Bednarik et al and Sinofsky et al do not elucidate the procedural steps required to approach the heart intravenously, to employ the jugular vein, since this is a large vessel in the neck, and to configure the ablative element to directionalize the energy or employ an cryosurgical element, since this does not manipulatively affect the method, thus producing a method such as claimed.

Claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al as applied to claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71, 72, 86, 87, 89-91, 96, 97, 100-105, 296, 298, and 299 above, and further in combination with Cox et al (WO '187) and the admitted prior art of including a

cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures. Cox et al (WO '187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Bednarek et al in combination with Sinofsky et al, or to employ the particular ablation steps of the combined teachings of Bednarek et al in combination with Sinofsky et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non-cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath,

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since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187), since this would enable the performance of beneficial cardiac procedures such as maze or to

employ the longitudinally translatable ablation element of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Swanson et al, since this can create longer lesions with a single ablation element, thus producing a method such as claimed.

Claims 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) or to employ the directional slidale probe in a sheath of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria or ventricles since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,033,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,962,586. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not

patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13, 19-64, and 68 of U.S. Patent No. 6,673,068. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,312,427. Although the conflicting claims are

not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 15, 16, 18, and 19 of U.S. Patent No. 6,245,062. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 22, 43, 47-49, 53, 54, 97, and 116 of U.S. Patent Application No. 10/211,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, and 14-17 of U.S. Patent Application No. 10/253,737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant

application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-42 of U.S. Patent Application No. 10/348,256. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second

patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent Application No. 10/897,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed July 17, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 1, 5-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Continuation of Disposition of Claims: Claims pending in the application are 1,5-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300.